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(54) Title: APPARATUS TO ASSIST A PATIENT'S BREATHING WITH A VARIABLE RAMP PERIOD TO RISE TO TREATMENT PRESSURE
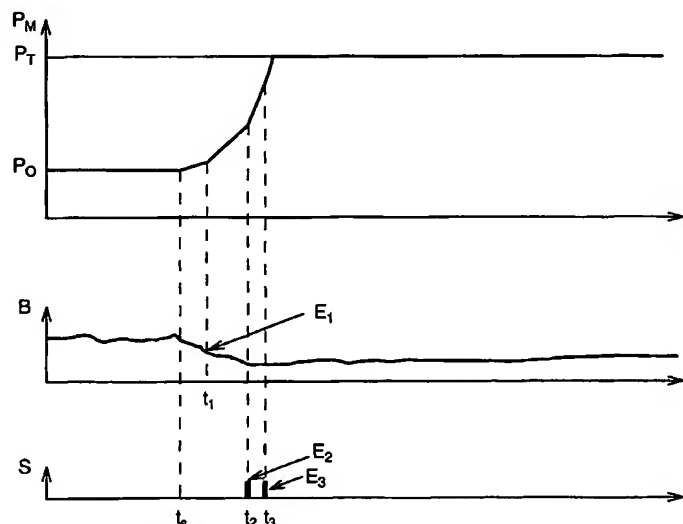
(57) Abstract: The invention concerns an apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask (20), comprising wherein a ramp module (10) connected to a control unit (2) in order to provide the control unit with the value of pressure PM to settle at said mask (20), so that when said apparatus (1) starts functioning, the pressure progressively rises until the pressure of treatment PTi the apparatus (1) further comprising a comparator connected to the ramp module (10), at least one means for detecting the patient's breathing parameters and sending them to said comparator, so that the comparator is able to determine that an event (E₁, E₂ or E₃) occurs in patient's breathing and to send the corresponding data to the ramp module (10) which provides the control unit (2) with a value of pressure PM that will speed up with respect of time, so that the rise of pressure at patient's mask (20) is accelerated.

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Apparatus to assist a patient's breathing with a variable ramp period to rise to treatment pressure

5 <u>Technical field</u>

This invention concerns the field of apparatus to assist a patient respiration and more specifically an apparatus bringing progressively to the pressure of treatment the air the patient is provided with.

10

<u>Background art</u>

In many treatments apparatus are used to provide patients with air. More frequently they are used for patients with a breathing deficiency caused for example by
15 the weakness of the breathing system or by obstructive apneas during the sleep. In those cases it is important to control the pressure of the air delivered to the patient. With respiratory insufficient patients, apparatus providing air at a higher pressure help to compensate the weakness of
20 the patients lungs. In the case of patients suffering of sleep apneas, providing the air at a higher pressure removes the obstruction of the upper airways.

The pressure of treatment is usually not strong enough to wake the patient up, but can prevent him from falling
25 asleep. An implementation of treatments apparatus is to wait for the patient to fall asleep before providing air under the treatment pressure. The classical solution is to have a ramp period, which is a slow increase of the delivered pressure from a low level to the treatment
30 pressure.

Still to enhance the comfort of the patient, it is disclosed in patent US5,492,113 and US5,970,975 an apparatus wherein several cycles of ramp are provided on patient's conscious demand. The cycles actuated after the
35 first cycle rise faster in pressure. All those ramps are

predetermined in shape and duration. The patient can also select a fastest shape of ramp or select one special shape in order to fall asleep more easily. This selection being made among different predetermined shapes of ramp. However,

5   such devices require from the patient a minimum of consciousness to activate the ramp cycles. This is not really very efficient to fall asleep and it is not possible when the patient as fallen asleep.

Moreover each ramp can not be modified during the time

10   when the ramp is activated.

Summary of the invention

The first object of the invention is to provide a ramp that would be able to modulate automatically, especially when

15   the patient falls asleep.

A second object of the invention is to provide in any case a maximum of time in rise of pressure, in order to apply the treatment in any case.

The invention thus concerns an apparatus to assist a

20   patient respiration by delivering air to a patient trough a mask, comprising:

- a blower to provide the patient with air under a treatment pressure,

- a control unit to adjust the pressure delivered by the

25   blower at the level of the patient's mask,

- a ramp module connected to the control unit in order to provide the control unit with the value of pressure P_M to settle at the mask, so that when the apparatus starts functioning, the pressure progressively rises until the

30   pressure of treatment P_T;

the apparatus comprising a comparator connected to the ramp module, means for detecting the patient's breathing parameters and sending them to said comparator, in order that in response to breathing parameters, the comparator is able to determine

35   that an event occurs in patient's breathing and to send the corresponding data to the ramp module which provides the

control unit with a value of pressure P_M that will speed up with respect of the time, so that the rise of pressure at patient's mask is accelerated.

In an implementation of the invention, the value of pressure P_M has always maximum and/or minimum limits so that the increase of pressure is also limited in minimum and/or maximum.

Such an apparatus has the advantage to generate a ramp period which can be modulated in the same ramp, according to patient's breathing parameters.

Brief description of figures

The purposes, objects and characteristics of the invention will become more apparent from the following description when taken in conjunction with the accompanying drawings in which:

Figure 1 represents the apparatus schema,

Figure 2 represents the pressure delivered to the patient's mask according to special events occurring in patient's breathing,

Figure 3 represents the domain of pressure increase, and

Figure 4 represents the block diagram for the ramp period.

Detailed description of the invention

The apparatus according to the present invention is able to generate a ramp period which can be modulated in respect of the time required by the patient for falling asleep.

The apparatus as represented in figure 1 comprises a blower 4 to provide the patient with air. This blower is connected to a tube 8 on a first extremity, the second extremity being connected to the mask 20 wherein the patient breathes. A control unit 2 provides the blower 10 with the electrical control required to enable the blower to function in order to set a given pressure at the patient's mask or blower's outlet. This pressure could be by a pressure

transducer 6 at the mask level or at the tube extremity, which is connected to the mask. A ramp module 10 is connected to the control unit 2 and to the pressure transducer 6. The ramp module provides the control unit 2 with the pressure at the patient's mask and with the pressure to settle at the patient's mask at the starting of the apparatus 1 functioning. During the treatment the control unit 2 is able to detect breathing events according to the pressure sensor 6 or any other way to evaluate or measure the patient's airflow. Such detection can be given by airflow sensors which provide the control unit with pressure parameters, the control units being thus able to detect that an event is occurring.

The apparatus according to the present invention is able to modulate the rise in pressure during one single ramp period, which is impossible to perform for apparatus of prior art. The apparatus comprises a ramp module 10 connected to the control unit 2 in order to provide the control unit with the value of pressure P_M to settle at the patient's mask, so that when said apparatus starts functioning, the pressure progressively rises until the pressure of treatment P_T. The apparatus comprises a comparator which is not represented in figure1 and that can be comprised in the control unit 2. This comparator is connected to the ramp module 10. The apparatus comprise also at least one means for detecting the patients breathing parameters and sending them to said comparator, in order that in response to said breathing parameters, the comparator is able according to determine that an event occurs in patient breathing and to send the corresponding data to the ramp module which provide the control unit 2 with a value of pressure P_M that will speed up in respect of the time, so that the rise of pressure at patient's mask is accelerated.

According to a preferred embodiment, the ramp module 10 provides the value of pressure P_M being a linear function of time wherein the increase coefficient K_{RP} is constant, said ramp module increasing that coefficient of a constant value K_E

when the control unit 2 send a data corresponding to the event which occurred.

In the apparatus 1 according to the present invention, a minimum speed of rise in pressure until the treatment pressure is set, as represented by the curve C_2 on figure 3. This minimum rise of pressure in respect of time is called in the present application a safety ramp C_2. Before the ramps period starts at the instant t_S, a minimum starting pressure P_0 is delivered. After the instant t_S, even if the patient is not asleep, the pressure at the mask will start rising. In any case at the instant t_T, the treatment pressure will be reached; this means that the curve C2 represents the minimum speed of rise in pressure. In a preferential implementation of the invention, the minimum speed of rise in pressure is proportional to time, the coefficient to rise in pressure according to time being K_{SR}. Also it can be set a maximum of rise in pressure as represented by the curve C_1 on figure 3. The maximum of rise in pressure can also be given a linear function of time. Between these two limits the rising of the pressure can be modulated by the control unit 2 in respect of the patient's falling asleep. That is to say that whenever any events occurs or not, the pressure provided at the patient's mask P_{PM} before the time of plain treatment t_T will be comprised between these two limits, this domain of pressure variations being represented in figure 3 by the hachures.

When a patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep. Another way to detect when the patient falls asleep is to detect the drop of frequency between the awake rate breathing and the awake breathing. As represented in figure 4 and according to a preferential implementation, the control unit 2 transmits the ramp module an output average pressure value P_M which is the pressure value required to patient's mask. When the patient is about to fall asleep, his respiration becomes stable. In that case the P_M value is increased, preferentially as a linear function of time, the

proportional coefficient being K_{RP}. If the pressure value P_M is inferior to the safety ramp pressure P_{SR}, the pressure P_M is set to the value of the safety ramp pressure P_{SR}, which is in a preferential implementation calculated by the module ramp 10
5   by multiplying the time spent from the beginning of the ramp routine to the present time by the coefficient K_{SP}. When the pressure value P_M equals or is superior to the treatment pressure P_T, the P_M pressure is maintained equal to the treatment pressure value P_T. On the contrary the control unit
10 2 checks again if the respiration is stable. This shows that until the patient falls asleep the P_M value will not be superior to the treatment pressure P_T, and will only equals it when the patient falls asleep or when the safety ramp reaches the treatment pressure value. This also shows that during the
15 ramp period, if the respiration is stable, the air provided can rise faster than the safety ramp.. In that case, the coefficient K_{RP} will be higher than the coefficient K_{SP}. The ramp module will thus enable to the control unit to accelerate the rise in pressure when the patients fall asleep and when no
20 events are detected.

An other implementation of the apparatus according to the present invention is that when the control unit detects an an event in patients breathing that shows an asleep state , the control unit will provide the ramp module 10 with the
25 information. The ramp module will thus increase again the rise in pressure.

The following are examples of ramp periods generated by the apparatus according the present invention.

30 Example 1: Variations of value P_M according to different events

Figure 2 represents one example of the apparatus functioning wherein three systems of coordinates are represented : pressure value PM as a function of time,
35 patient's breathing B as a function of time and snoring S as a function of time. At a time t_s, the ramp module 10 activates

the rise in pressure. At time t_1 as a slowdown E_1 in breathing is detected, the rise in pressure is accelerated by the ramp module 10. Then at time t_2 snoring E_2 is detected. Thus, the rise in pressure is accelerated again by the ramp module. As

5 at time t_3 a snoring E_3 is still detected the ramp module still accelerates the rise in pressure. As represented on figure 2, the preferred embodiment is a linear rise in pressure. Thus at time t_S, the coefficient K_{RP} of rise in pressure is constant. Each time an event is detected the

10 module ramp adds a given constant value K_E to this coefficient, the slope of the linear function being thus accentuated at each event. This will last until the treatment pressure P_T is raised. Then the ramp is completed and the control unit applies the treatment pressure to the patient's

15 mask. The value K_E can be set by the physician in a non volatile memory and can be different according to the event detected.

Example 2 : Example of calculating the value P_M

20 In this example the treatment pressure P_T is of 10 hecto pascal (hPa). The initial pressure P_0 of the air provided at patient's mask is 4 hPa. A physician has set that the ramp will start at a time ts of 2 minutes and has set the initial coefficient K_{RP} at 0.2 hPa per minute (hPa/mn). The physician

25 also set that when a snoring is detected K_E equals 1 hPa when the breath rate is below a set threshold.

When the apparatus starts the control units supply the blower in order to set at the patient's mask a pressure of 4 hPa. After 2 minutes, the ramp module starts increasing the

30 value P_M. As no events occurs, the coefficient K_{RP} stays at 0.2 hPa. After 10 minutes the value P_M is of 5.6 hPa (8 minutes multiplied by 0.2 hPa/mn and added to the 4 hPa). After these ten minutes, the patient's breath is below threshold. The ramp module adds the corresponding K_E value to the coefficient K_{RP},

35 which thus equals 1.2 hPa/mn. The treatment pressure is thus raised in about 13 minutes and 40 seconds.

CLAIMS

1. An apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask (20), comprising :
- a blower (4) to provide the patient with air under a treatment pressure,
- a control unit (2) to adjust the pressure delivered by said blower at the level of said mask,
- a ramp module (10) connected to the control unit in order to provide the control unit with the value of pressure P_M to settle at said mask, so that when said apparatus starts functioning, the pressure progressively rises until the pressure of treatment P_T;
characterized in that it comprises a comparator connected to the ramp module, at least one means for detecting the patient's breathing parameters and sending them to said comparator, in order in response to said breathing parameters, that the comparator is able to determine that an event (E_1, E_2 or E_3) occurs in patient's breathing and to send the corresponding data to the ramp module which provides the control unit with a value of pressure P_M that will speed up with respect of time, so that the rise of pressure at patient's mask is accelerated.

2. The apparatus (1) according to claim 1, wherein said ramp module provides the value of pressure P_M being a linear function of time wherein the increase coefficient K_{RP} is constant, said ramp module increasing that coefficient of a constant value K_E when the control unit (2) send a data corresponding to said event (E_1, E_2 or E_3).

3. The apparatus according claim 1 or 2, wherein the value of pressure P_M has always maximum and/or minimum limits so that the increase of pressure is also limited in minimum and/or maximum.

4. The apparatus according claim 2 and 3, wherein said ramp module (10) comprises a memory (12) where a minimum coefficient K_{SRP} is stored, said ramp module always maintaining the coefficient K_{RP} equal or superior to said minimum coefficient K_{SRP}, so that the ramp module provides the control unit (2) with a value of pressure P_M always superior to a minimum limit.

5. The apparatus (1) according to claim 2 and 3, wherein said ramp module (10) comprises a memory (12) where a maximum coefficient K_{MRP} is stored, said ramp module always maintaining the coefficient K_{RP} equal or inferior to said maximum coefficient K_{MRP}, so that the ramp module provides the control unit (2) with a value of pressure P_M always inferior to a maximum limit.

6. The apparatus according to any of the previous claims, wherein said means (6) for detecting the patient's breathing parameters enable the control unit (2) to compute the airflow at patient's mask (20), said comparator determining that an event (E_1, E_2 or E_3) is occurring with the airflow parameters or shape.

7. The apparatus according to any one of the previous claims, wherein the ramp module (10) increases the value of pressure P_M when an anomaly, such as snoring or apnea, in patient's breathing is detected.

8. The apparatus according to any one of the previous claims, wherein the ramp module (10) increases the value of pressure P_M when the patient's breathing parameters correspond to a drop between awake breathing and asleep breathing or when they correspond to a stable frequency of breathing.
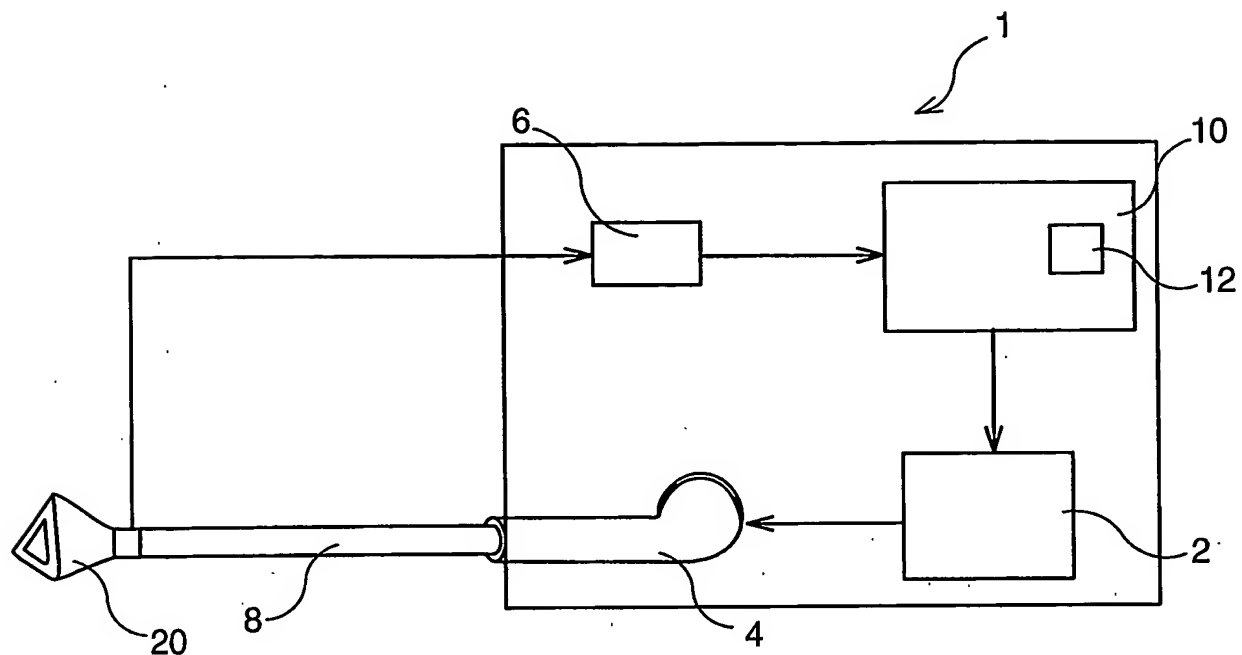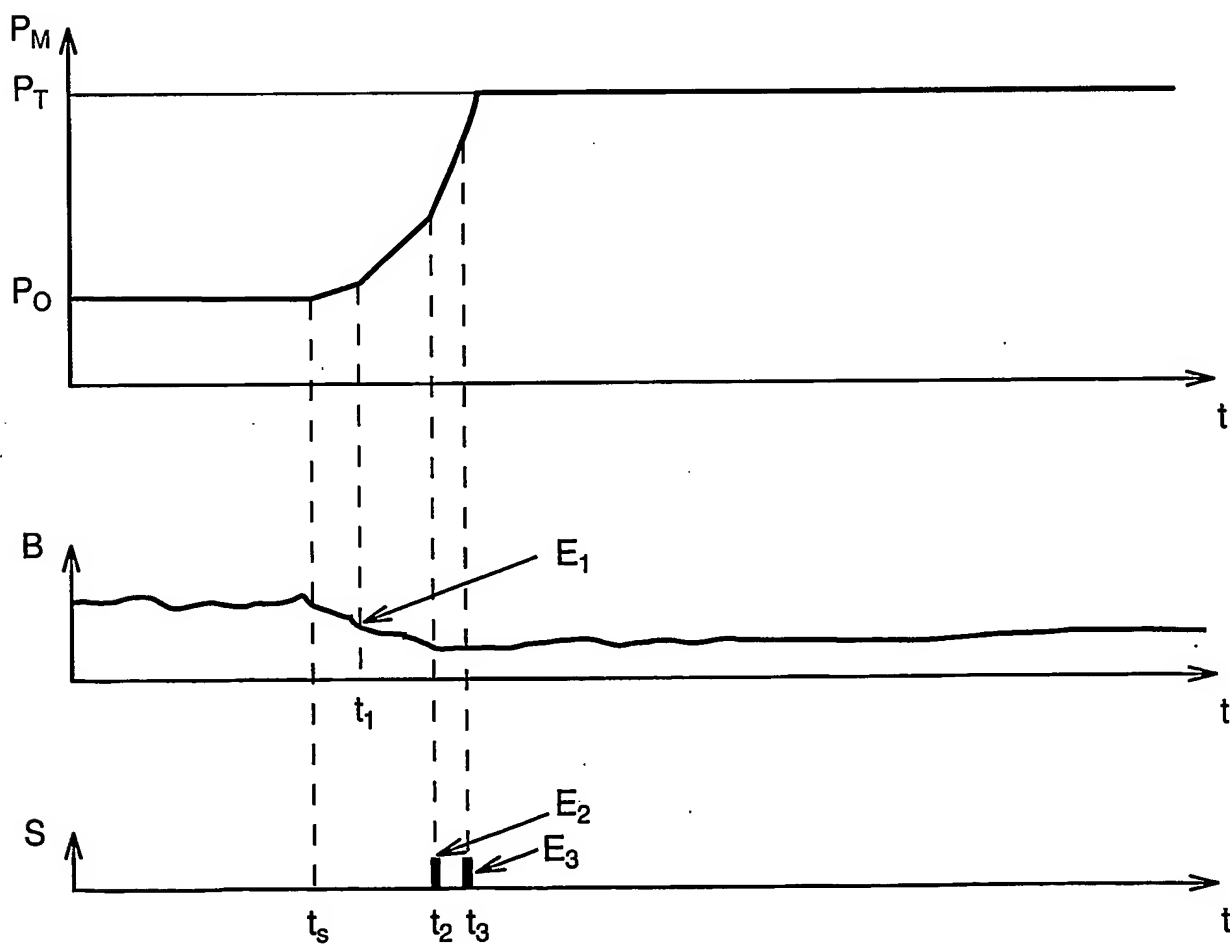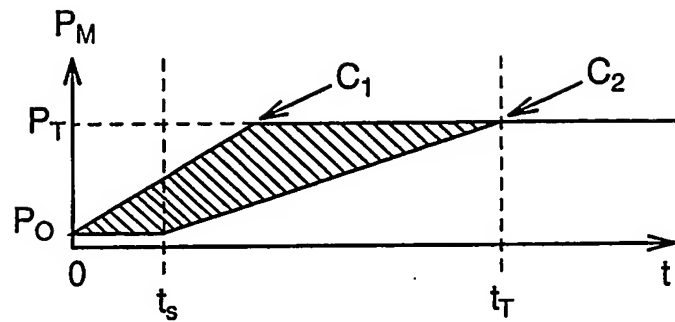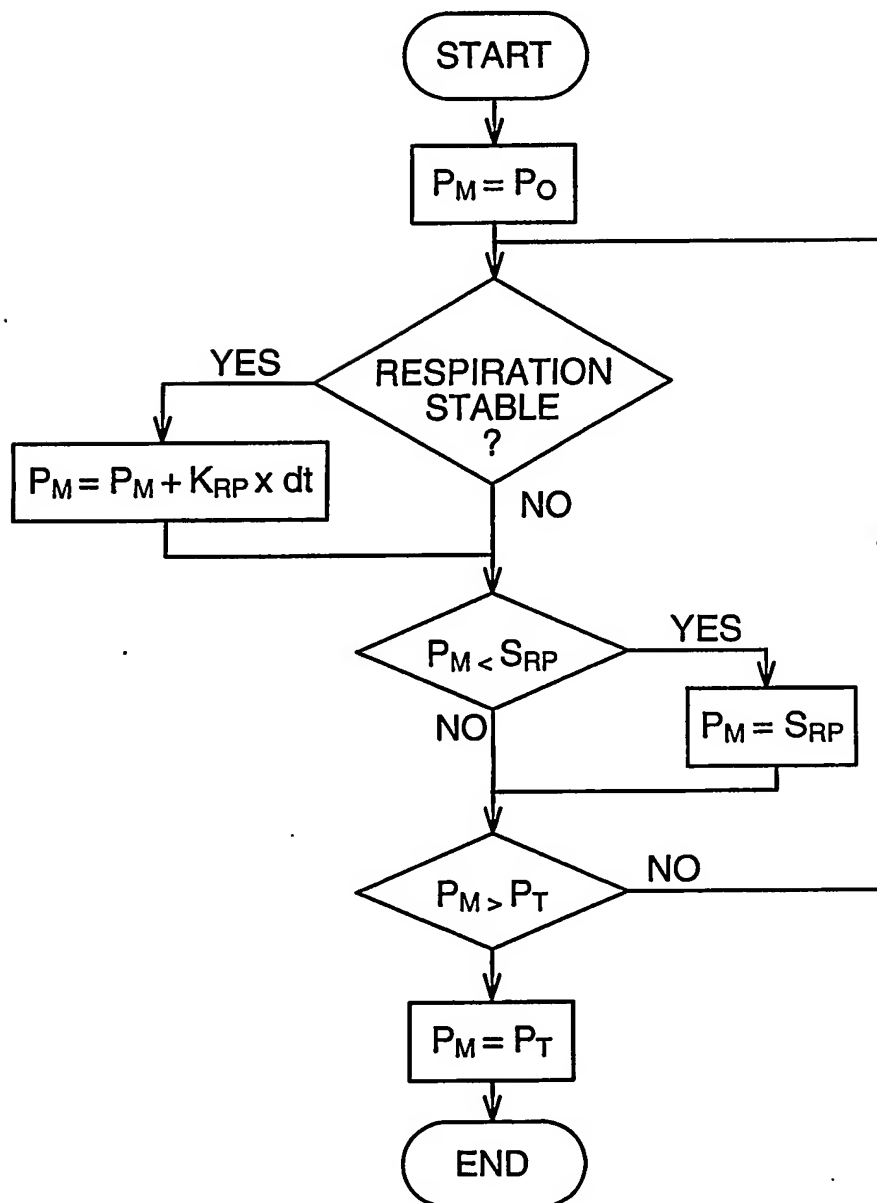
FIG. 1

FIG. 2

FIG. 3

FIG. 4

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7   A61M16/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7   A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
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[X] Further documents are listed in the continuation of box C.   [X] Patent family members are listed in annex.

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Date of the actual completion of the International search	Date of mailing of the International search report
16 June 2003	03/07/2003

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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